Section L
510(k) Summary

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1. Applicant's Name and Address

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Contact Person: Lisa Quaglia
Director, Regulatory Affairs

MAY 22 2009

2. Name of the Device

Trade Name:	Straumann® MembraGel
Common Name:	Bone grafting material
Classification Name:	Barrier, Synthetic, Intraoral
Regulation Number:	§872.3930

3. Legally Marketed Device to which Equivalence is Claimed (Predicate Device)

BIO-GIDE® Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration (K050446)

ATRISORB® FreeFlow™ GTR Barrier (K982865)

4. Description of the Device

Straumann® MembraGel is a sterile, synthetic, biodegradable barrier membrane for single patient use. It is intended to aid in the regeneration and integration of oral tissue components in guided bone regeneration procedures.

5. Intended Use of the Device

Straumann® MembraGel is a biodegradable, synthetic, in situ forming hydrogel material. It is intended to aid in the regeneration and integration of oral tissue components in guided bone regeneration procedures. This includes the surgical treatment of peri-implant defects, bone defects, deficient alveolar ridges, and extraction sockets.

Because Straumann® MembraGel is not self supporting it must be used in combination with a bone graft material in order to maintain space under the membrane.

6. Technological Characteristics

The proposed Straumann® MembraGel is substantially equivalent to the currently marketed devices. The intended use is the same as the intended uses of the predicate devices. The proposed hydrogel has the similar material composition, basic design and fundamental operating principles to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

Institut Straumann AG
C/o Ms. Lisa M. Quaglia
Regulatory Affairs Director
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K082111
Trade/Device Name: *Straumann® MembraGel*
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: May 21, 2009
Received: May 22, 2009

Dear Ms. Quaglia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082111

Indication for Use Statement

Device Name: Straumann® MembraGel

Indications for Use:

Straumann MembraGel is a biodegradable, synthetic, in situ forming hydrogel material. It is intended to aid in the regeneration and integration of oral tissue components in guided bone regeneration procedures. This includes the surgical treatment of peri-implant defects, bone defects, deficient alveolar ridges, and extraction sockets.

Because Straumann MembraGel is not self supporting it must be used in combination with a bone graft material in order to maintain space under the membrane.

Kevin Mulley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 082111

Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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